

3.1 VACCINE

† This can be extended up to -56 days only if an additional procedure is needed to establish that the patient is melanoma-free prior to randomization

* **History/Physical Exam, Vital Signs, Performance Status, Routine Labs, Chest X-Ray q2 months in year 2, q3 months in year 3, then q6 months through year 5; CT or MRI at 18, 24, and 36 months (chest x-ray omitted if CT/MRI scheduled)**

XA 0.1 mL of a 1:10 dilution of Tice BCG (Tice-A) mixed with vaccine

XB 0.1 mL of a 1:100 dilution of Tice BCG (Tice-B) mixed with vaccine

XC 0.1 mL of a 1:1000 dilution of Tice BCG (Tice-C) mixed with vaccine

✦ This can be extended up to -34 days if an additional procedure is needed to establish that the patient is melanoma-free prior to randomization

Routine Labs: hematology (CBC with differential, platelet count), BUN or creatinine, LDH, SGOT, alkaline phosphatase, electrolytes

Xe End of Treatment Month

Figure 1